

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kevin J. Tracey and Haichao Wang

Continuation of

Application No.: 10/300,068

Filed: November 20, 2002

Title: ANTAGONISTS OF HMG1 FOR TREATING INFLAMMATORY CONDITIONS

Date: <u>11-21-03</u>
EXPRESS MAIL LABEL NO. <u>EV 21495035045</u>

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☐ Copies of the cited references are enclosed.
 - ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☒ Copies of the cited references are enclosed except those entered in prior U.S. Application Nos. 10/300,068, filed November 20, 2002, 10/210,747, filed July 31, 2002, 09/503,632 (now issued as U.S. Patent No. 6,468,533), filed February 14, 2000 and 09/248,574 (now issued as U.S. Patent No. 6,303,321), filed February 11, 1999. These earlier applications contain copies of cited references AA-AC, AL-AP, AR-AZ, AR2-AZ2, AR3-AZ3, AR4 and AS4.
 - ☒ The listed references (AY2 and AR3) were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. 10/300,072, by Kevin J. Tracey, Huan Yang, Howland Shaw Warren, Jr., and Mitchell P. Fink, filed November 20, 2002, Docket No.: 3268.1001-005.

_____ U.S. Patent Application No. 10/210/747, by Kevin J. Tracey and Haichao Wang, filed July 31, 2002, Docket No.: 3268.1000-009.

_____ U.S. Patent Application No. 10/242,056, by Kevin J. Tracey and Haichao Wang, filed September 11, 2002, Docket No.: 3268.1000-010.

_____ U.S. Patent Application No. 10/300,068, by Kevin J. Tracey and Haichao Wang, filed November 20, 2002, Docket No.: 3268.1000-011.

Examiner

Date

- [X] A copy of U.S. Patent Application No.: 10/300,068, including current claims, is enclosed. The other three above-cited applications, including the current claims, were filed in prior application, U.S. Application No.: 10/300,068.
- [] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. , to which priority under 35 U.S.C. 120 is claimed.


The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated:

November 21 2003

October 30, 2003

(Use several sheets if necessary)

APPLICATION NO.
Continuation of 10/300,068

APPLICANT

Kevin J. Tracey and Haichao Wang

FILING DATE

CONFIRMATION NO.

GROUP

EXAM-
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REF.
NO.

DOCUMENT NUMBER

ISSUE DATE /
PUBLICATION DATE

NAME

AA

US 6,303,321 B1

10/16/01

Tracey, *et al.*

AB

US 6,448,223 B1

09/10/02

Tracey, *et al.*

AC

6,468,533 B1

10/22/02

Tracey *et al.*

EXAMINER

DATE CONSIDERED

October 30, 2003

(Use several sheets if necessary)

APPLICATION NO.
Continuation of 10/300,068

APPLICANT
Kevin J. Tracey and Haichao Wang

FILING DATE

CONFIRMATION NO.

GROUP

FOREIGN PATENT DOCUMENTS

[illegible]

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION October 30, 2003 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3268.1000-012		APPLICATION NO. Continuation of 10/300,068	
	APPLICANT Kevin J. Tracey and Haichao Wang			
	FILING DATE	CONFIRMATION NO.	GROUP	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
AR	Zhang, M. <i>et al.</i> , "Tumor Necrosis Factor", in <i>The Cytokine Handbook</i> , (Academic Press Limited), Third Edition, pp. 517-547 (1998).
AS	Johns, E.W., <i>et al.</i> "History, Definitions and Problems", in <i>The HMG Chromosomal Problems</i> , (Academic Press), London: Chapter 1, pp. 1-7 (1982).
AT	Landsman, D., <i>et al.</i> , "A Signature for the HMG-1 Box DNA-Binding Proteins", <i>BioEssays</i> , 15(8): 539-546 (1993).
AU	Baxevanis, A.D., <i>et al.</i> , "The HMG-1 Box Protein Family: Classification and Functional Relationships", <i>Nucleic Acids Res.</i> , 23(9):1604-1613 (1995).
AV	Merenmies, J., <i>et al.</i> , "30-kDa Heparin-Binding Protein of Brain(Amphoterin) Involved in Neurite Outgrowth", <i>J. Biol. Chem.</i> , 266(25): 16722-16729 (1991).
AW	Milev, P., <i>et al.</i> , "High Affinity Binding and Overlapping Localization of Neurocan and Phosphacan/Protein-Tyrosine Phosphatase - ζ/β with Tenascin -4, Amphotericin, and the Heparin-Binding Growth-Associated Molecule", <i>J. Biol. Chem.</i> , 273(12):6998-7005 (1998).
AX	Salmivirta, M., <i>et al.</i> , "Neurite Growth-Promoting Protein (Amphoterin, p 30) Binds Syndecan", <i>Exp. Cell Res.</i> , 200: 444-451 (1992).
AY	Melloni, E., <i>et al.</i> , "Identity in Molecular Structure Between "Differentiation Enhancing Factor" of Murine Erythroleukemia Cells and the 30 kD Heparin-Binding Protein of Developing Rat Brain", <i>Biochem. Biophys. Res. Commun.</i> , 210(1): (1995).
AZ	Melloni, E., <i>et al.</i> , "Extracellular Release of the 'Differentiation Enhancing Factor', and a HMG1 Protein Type, is an Early Step in murine Erythroleukemia Cell Differentiation", <i>FEBS Lett.</i> , 368: 466-470 (1995).
AR2	Mohan, P.S., <i>et al.</i> , "Sulfoglycolipids Bind to Adhesive Protein Amphoterin (p30) in the Nervous System", <i>Biochem. Biophys. Res. Commun.</i> , 182(2)(1992).
AS2	Yamawaki, M., <i>et al.</i> , "Generation and Characterization of Anti-Sulfoglucuronosyl Paragloboside Monoclonal Antibody NGR50 and Its Immunoreactivity with Peripheral Nerve", <i>J. Neurosci. Res.</i> , 44: 586-593 (1996).
AT2	Vassalli, J., <i>et al.</i> , "The Plasminogen Activator/Plasmin System", <i>J. Clin. Invest.</i> , 88: 1067-1072 (1991).

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION October 30, 2003 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3268.1000-012		APPLICATION NO. Continuation of 10/300,068	
	APPLICANT Kevin J. Tracey and Haichao Wang			
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AU2	Parkkinen, J., <i>et al.</i> , "Interactions of Plasminogen and Tissue Plasminogen Activator (t-PA) with Amphotericin", <i>J. Biol. Chem.</i> , 266(25): 16730-16735 (1991).	
AV2	Redlitz, A., <i>et al.</i> , "Receptors for Plasminogen and t-PA: An Update", <i>Baillière's Clinical Haematology</i> , 8(2): 313-327 (1995).	
AW2	Sobajima, J., <i>et al.</i> , "Novel Autoantigens of Perinuclear Anti-Neutrophil Cytoplasmic Antibodies (P-ANCA) in Ulcerative Colitis: Non-histone Chromosomal Proteins, HMG1 and HMG2," <i>Clin. Exp. Immunol.</i> , 107:135-140 (1997).	
AX2	Sobajima, J., <i>et al.</i> , "Anti-Neutrophil Cytoplasmic Antibodies (ANCA) in Ulcerative Colitis: Anti-Cathepsin G and a Novel Antibody Correlate With a Refractory Type," <i>Clin. Exp. Immunol.</i> , 105:120-124 (1996).	
AY2	Sparatore, B., <i>et al.</i> , "Extracellular High-mobility Group 1 Protein Is Essential for Murine Erythroleukaemia Cell Differentiation," <i>Biochem. J.</i> , 320:253-256 (1996).	
AZ2	Tomita, N., <i>et al.</i> , "Direct in Vivo Gene Introduction into Rat Kidney," <i>Biochem. Biophys. Res. Commun.</i> , 186(1):129-134 (1992).	
AR3	Wang, H., <i>et al.</i> , "HMG-1 as a Late Mediator of Endotoxin Lethality in Mice," <i>Science</i> 285:248-251 (1999).	
AS3	Abraham, E., <i>et al.</i> , "Cutting Edge: HMG-1 as a Mediator of Acute Lung Inflammation," <i>J. Immunol.</i> , 165:2950-2954 (2000).	
AT3	Andersson, U., <i>et al.</i> , "High Mobility Group 1 Protein (HMG-1) Stimulates Proinflammatory Cytokine Synthesis in Human Monocytes," <i>J. Exp. Med.</i> , 192:565-570 (2000).	
AU3	Bianchi, M.E., <i>et al.</i> , "The DNA Binding Site of HMG1 Protein is Composed of Two Similar Segments (HMG Boxes), Both of Which Have Counterparts in Other Eukaryotic Regulatory Proteins," <i>EMBO J.</i> , 11(3): 1055-1063 (1992).	
AV3	Bustin, M. "Revised Nomenclature for High Mobility Group (HMG) Chromosomal Proteins," <i>Trends Biochem. Sci.</i> , 26:152-153 (2001).	

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	FILING DATE		CONFIRMATION NO.	GROUP

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AW3	Degryse, B., <i>et al.</i> , "The High Mobility Group (HMG) Boxes of the Nuclear Protein HMG1 Induce Chemotaxis and Cytoskeleton Reorganization in Rat Smooth Muscle Cells," <i>J. Cell Biol.</i> , 152:1197-1206 (2001).
	AX3	Wang, H., <i>et al.</i> , "Proinflammatory Cytokines (Tumor Necrosis Factor and Interleukin 1) Stimulate Release of High Mobility Group Protein-1 by Pituicytes," <i>Surgery</i> , 126:389-392(1999).
	AY3	Falciola, L., <i>et al.</i> , "High Mobility Group 1 Protein is Not Stably Associated with the Chromosomes of Somatic Cells," <i>J. Cell Biol.</i> , 137 (1):19-26 (1997).
	AZ3	Vanderbilt, J.N., <i>et al.</i> , "Monoclonal Antibodies as Probes for the Complexity, Phylogeny, and Chromatin Distribution of High Mobility Group Chromosomal Proteins 1 and 2," <i>J. Biol. Chem.</i> , 260(16):9336-9345 (1985).
	AR4	Bustin, M., <i>et al.</i> , "Antigenic Determinants of High Mobility Group Chromosomal Proteins 1 and 2," <i>Biochem.</i> , 21:6773-6777 (1982).
	AS4	Tsuneoka, M., <i>et al.</i> , "Monoclonal Antibody Against Non-Histone Chromosomal Protein High Mobility Group 1 Co-Migrates With High Mobility Group 1 Into the Nucleus," <i>J. Biol. Chem.</i> , 261(4):1829-1834 (1986).

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